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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/540,266

12/07/2005

Kazushi Oshino

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7590

07/10/2009

OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER

ROBERTS, LEZAH

ART UNIT

PAPER NUMBER

1612

NOTIFICATION DATE

DELIVERY MODE

07/10/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/540,266	Applicant(s) OSHINO ET AL.	
	Examiner LEZAH W. ROBERTS	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
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| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>23 June 2005 and 05 Sept 2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Election of Species

Applicant's election without traverse of a system comprising a composition comprising component (A), (C), and (D), and a separate composition comprising component (B) in the reply filed on April 22, 2009 is acknowledged.

Claims

Claim Rejections - 35 USC § 103 - Obviousness

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winston et al. (US 5,817,296).

Winston et al. disclose an oral composition comprising two-part compositions. The two parts are mixed and immediately applied to the teeth being treated (col. 4, lines 33-35), encompassing claims 2 and 8. One component comprises a calcium salt including calcium glycerophosphate (col. 6, lines 50-52), encompassing components (A) and (C) of the instant claims. The calcium salt comprises 0.05 to 15% of the compositions (col. 10, lines 27-29), encompassing claim 7 when the salt is calcium glycerophosphate. The compositions also comprise at least one fluoride source. These include sodium fluoride and sodium monofluorophosphate (col. 8, lines 3-16). The fluoride source may comprise Sodium monofluorophosphate may be added into the same component as the calcium salt. It is noted that there is a potential loss of fluoride (col. 8, lines 18-24). The at least one fluoride releasing agent comprises 0.01 to 5.0% of

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the second component. The two components are mixed before use. The mixing will precipitate calcium phosphate, calcium fluoride and calcium fluoro-apatite (col. 12, lines 50-65), encompassing claim 3. The reference differs from the instant claims insofar as it does not disclose an example comprising a monofluorophosphate supplying compound and an additional fluoride source.

The reference discloses “at least one water-soluble fluoride releasing compound” and therefore it may be concluded that a mixture of fluoride releasing compounds may be used in the component not comprising calcium, the second component. Generally, it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for same purpose, in order to form a third composition to be used for the very same purpose. The idea for combining them flows logically from their having been individually taught in the prior art. See MPEP 2144.06. That being said, it would have been obvious to one of ordinary skill in the art to have combined two fluorides such as a monofluorophosphate and a fluoride such as sodium fluoride in the second component motivated by the desire to use two compounds known to have the same function.

In regards to the elected species of “a system comprising a composition comprising component (A), (C), and (D), and a separate composition comprising component (B)”, monofluorophosphate may be added to the component comprising the calcium salt. It would have been obvious to have added an additional fluoride salt to the second component motivated by the desire to ensure that enough fluoride was present in the composition due the potential loss of fluoride when monofluorophosphate was combined with a calcium salt as disclosed by the reference.

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In regards to claim 6, it is reasonable to conclude that compositions will have these properties because the compositions of the reference may comprise substantially the same components of the instant claims and therefore upon mixing the two components when calcium glycerophosphate, monofluorophosphate and a fluoride such as sodium fluoride are present, calcium fluoride will be formed as well as secondary aggregates of calcium fluoride fine particles.

In regards to claim 5 and the particle size of the calcium fluoride formed from mixing the two components, it is reasonable to conclude that the two components will yield particles the same size as those recited in the instant claims because the same calcium salts and fluoride providing compounds used in the reference are the same and are used in the same amounts as those recited by the instant claims and therefore should yield substantially the same precipitates of the same substantially the same size.

2) Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishihara et al. (US 6,770,265).

Ishihara et al. disclose tooth surface treatment material comprising two solutions. One solution comprises 2 to 30% by weight of a calcium salt (col. 2, lines 47-57), encompassing claim 7. The calcium salts that may be used include calcium glycerophosphate (col. 4, lines 5 & 6), encompassing claims 9 and 10. A fluoride salt is added to the solution not comprising a calcium salt. The fluoride salts include sodium fluoride, potassium fluoride and sodium monofluorophosphate. The fluoride salts

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comprise 0.0001 to 3% by weight, encompassing claim 7. The fluoride salts may be used singly or in combination with one another (col. 5, lines 15-25). Each solution is applied one after the other (col. 7, lines 1-10), encompassing claims 2 and 8. In the presence of fluoride, fluoroapatite is formed (col. 9, lines 42-55), which encompasses a calcium fluoride as recited in claim 3.

The reference differs from the instant claims insofar as it does not disclose an example comprising a monofluorophosphate supplying compound and an additional fluoride source.

The reference discloses "the fluoride salts may be used singly or in combination with one another" and therefore it may be concluded that a mixture of fluoride releasing compounds may be used in the component not comprising calcium, the second component. That being said, it would have been obvious to one of ordinary skill in the art to have combined two fluorides such as a monofluorophosphate and a fluoride such as sodium fluoride in the second component motivated by the desire to use two fluoride salts in combination as suggested by the reference.

In regards to claim 6, it is reasonable to conclude that compositions will have these properties because the compositions of the reference may comprise substantially the same components of the instant claims and therefore upon mixing the two solutions when calcium glycerophosphate, monofluorophosphate and a fluoride such as sodium fluoride are present, it is reasonable to conclude that calcium fluoride will be formed as well as secondary aggregates of calcium fluoride fine particles.

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In regards to claim 5 and the particle size of the calcium fluoride formed from mixing the two components, it is reasonable to conclude that the two components will yield particles the same size as those recited in the instant claims because the same calcium salts and fluoride providing compounds used in the reference are the same and are used in the same amounts as those recited by the instant claims and therefore should yield substantially the same precipitates of the same substantially the same size.

Claims 1-12 are rejected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612